

Atty Dkt 2300-1087 **PATENT**

"Express Mail" Mailing Label No. TB 7599 1321 X US
"Express Mail" Mailing Label No. TB75991321 X US Date of Deposit June 7, 1995
I hereby certify that this paper or fee is being deposited with the United States Postal Service
"Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated
above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C.
20231. Gail Wardwell
Typed or Printed Name of Person Mailing Paper or Fee
Sail Wardweel
Signature of Person Mailing Paper or Fee

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

COWGILL et al.

Serial No.: Unassigned

Group Art Unit: Unassigned

Filing Date: on even date herewith

Examiner: Unassigned

Title:

METHODS FOR PURIFYING

AUTHENTIC IGF FROM YEAST

HOSTS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

The following is an Information Disclosure Statement submitted for the Examiner's consideration.

Applicants respectfully request that the Examiner review and make of record the references identified below. A Form PTO-1449 listing the references accompanies this paper. Applicants would appreciate the Examiner's initialling and

returning the form to indicate that the references have been reviewed and made of record.

References

- U.S. Patent 5,231,178 to Holtz et al., issued Jul. 27, 1993;
- U.S. Patent 5,324,639 to Brierly et al., issued Jun. 28, 1994;
- PCT Application WO 92/12993 published Aug. 6, 1992;
- K. Axelsson et al., "Disulfide arragnement of human insulin-like growth factor I derived from yeast and plasma" Eur. J. Biochem. (1992) 206:987-994;
- J.Y. Chang et al., "Single-Step Solubilization and Folding of IGF-1 Aggregates from *Escherichia coli*" Protein Folding: in vivo and in vitro (American Chemical Society, 1993) pp. 178-188;
- S. Elliott et al., "Yeast-Derived Recombinant Human Insulin-Like Growth Factor I: Production, Purification, and Structural Characterization" *J. Protein Chem.* (1990) 2:95-104;
- G. Forsberg et al., "Separation and characterization of modified variants of recombinant human insulin-like growth factor I derived from a fusion protein secreted from *Escherichia coli*" *Biochem. J.* (1990) 271:357-363;
- R.A. Hart et al. "Effect of environment on insulin-like growth factor I refolding selectivity" *Biotechnol. Appl. Biochem.* (1994) 20:217-234;
- K.R. Hejnaes et al., "Development of an optimized refolding process for recombinant Ala-Glu-IGF-I" *Prot. Eng.* (1992) <u>5</u>:797-806;
- S. Hober et al., "Disulfide Exchange Folding of Insulin-like Growth Factor I" *Biochem.* (1992) 31:1749-1756;
- H. Meng et al., "Reduction Studies on Bacterial Recombinant Somatomedin C/Insulin-like Growth Factor" J. Chromatog. (1988) 443:183-192;
- J.A. Miller et al., "Oxidative Refolding of Insulin-like Growth Factor I Yields Two Products of Similar Thermodynamic Stability: A Bifurcating Protein-Folding Pathway" *Biochemistry* (1993) 32:5203-5213;

L.O. Narhi et al., "role of Native Disulfide Bonds in the Structure and Activity of Insulin-like Growth Factor I: Genetic Models of Protein-Folding Intermediates" *Biochemistry* (1993) 32:5214-5221;

M. Niwa et al., "Chemical Synthesis, cloning, and Expression of Genes for Human Somatomedin C (Insulin-like Growth Factor I) and ⁵⁹Val-Somatomedin C" Ann. NY Acad. Sci. (1986) 469:31-52; and

E. Samuelsson et al. "Enhanced in Vitro Refolding of Insulin-like Growth Factor I using a Solubilizing Fusion Partner" *Biochemistry* (1994) 33:4207-4211.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of U.S.C. § 102.

The Office is hereby authorized to charge any additional fees which may be required by this paper, or to credit any overpayment, to our Deposit Account No. 18-0580. A duplicate copy of this paper is enclosed.

Respectfully submitted,

Roberta L. Robins

Registration No. 33,208

REED & ROBINS 635 Bryant Street Palo Alto, CA 94301 Telephone: (415) 617-8999

Fax: (415) 327-3231